

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Jussi NURMI et al.

Serial Number: 10/579,137

Group Art Unit: 1637

Filed: May 15, 2006

Examiner: Mummert, Stephanie K.

For: NUCLEIC ACID AMPLIFICATION ASSAY AND ARRANGEMENT THEREFOR

REQUEST FOR RECONSIDERATION

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22314

August 24, 2009

Sir:

In response to the Official Action mailed May 12, 2009, a Petition for a one month Extension of Time being submitted herewith, please reconsider this application in view of the following remarks. Claims 18-30 are pending.

Examiner Mummert is thanked for the courtesies extended to the undersigned during a personal interview held earlier today. The Examiner Interview Summary Record accurately reflects the substance of the interview.

The 35 U.S.C. § 103(a) rejection of claims 18-30 over U.S. Patent No. 6,568,286 to Cabuz in view of Iqbal et al., 15 Biosensors & Bioelectronics 549 (2000) is traversed. The claimed assay includes retaining biological particles containing an analyte

of interest on a filter, followed by removing the biological particles from the filter by a flush flow in a second direction opposite said first direction, and then analyzing biological particles contained in the flush flow by means of a nucleic acid amplification assay.

The cited combination of references fails to raise a prima facie case of obviousness because the combined disclosures of these references fails to disclose or suggest the claimed assay.

1. Cabuz fails to disclose or suggest retaining biological particles containing an analyte(s) of interest on a filter

Col. 9, lines 4-67, cited by the Patent Office, do not disclose or suggest retaining biological particles containing the analyte(s) of interest on a filter. Instead, Col. 9, lines 4-22 of Cabuz discloses two uni-directional modes of operation in which a fluid to be sampled is pumped through a mesopump sensor. In the first unidirectional embodiment, a fluid to be sampled is pumped past the only sensor without any filtration. In the second unidirectional embodiment, the fluid to be sampled is pumped past two filters before passing through the sensor. In neither unidirectional embodiment is a biological particle containing an analyte of interest retained on a filter.

Col. 9, lines 23-44 of Caduz next discuss modes of handling the clogging of filters by contaminant particles, not analytes of interest. See Col. 9, lines 18-22 and lines 29-36.

Col. 9, lines 45-67 of Cabuz discuss sensor saturation in which an analyte or other material is adsorbed onto sensor 303. Two methods are suggested to overcome this problem. First, a purifying reverse flow is suggested until the analyte is desorbed from sensor 303. However, there is no mention of desorbing an analyte from filters 302 or 306.

During the interview, the Examiner suggested the Cabuz sensor 303 can be interpreted broadly to mean a filter. It is respectfully submitted the terms "sensor" and "filter" have different meanings to one of ordinary skill in the art, and that Cabuz itself uses these terms (sensor and filter) rather than a single term to encompass both. In short, it is unreasonable to interpret Cabuz' "sensor" as a "filter".

The second method suggests bi-directional "shallow breathing" in which the analyte is drawn past the sensor, but is then expelled by reversing its direction. The goal is to draw the sample past the sensor but not into the mesopump, in order to reduce fouling of

the pump (Col. 9, lines 65-67). There is no disclosure or suggestion of retaining an analyte on a filter.

The Patent Office also cites Col. 10, line 65 to Col. 11, line 10 and Fig. 8 as showing the retention of an analyte on a filter. However, these portions of Cabuz also fail to disclose this step of the claimed assay. Instead, Cabuz expressly teaches bringing the sample fluid past sensor 354 before passing through impact filter 360 and then into pump chamber 364, before the fluid direction is reversed, and its flows back through impact filter 360 and then sensor 354. There is no disclosure (or suggestion) of retaining particles containing an analyte on filter 364.

In short, one of ordinary skill in the art would not be motivated by, or find any apparent reason from, Cabuz to retain biological particles containing an analyte of interest on a filter.

2. Cabuz fails to disclose or suggest removing the biological particles from the filter by a flush flow in a second direction opposite said first direction

As discussed in detail above, Cabuz fails to disclose retaining biological particles containing an analyte of interest on a filter. Accordingly, Cabuz also fails to disclose removing such particles from a filter by a flush flow in a second direction opposite the first direction.

3. Cabuz fails to disclose or suggest analyzing biological particles contained in the flush flow by means of a nucleic acid amplification

Even assuming, arguendo, the Cabuz sensor can be reasonably interpreted as a filter, one of ordinary skill in the art has no motivation to analyze the analyte desorbed/removed from Cabuz sensor. Instead, this analyte - adsorbed over time - would be considered waste to be discarded rather than a sample to be analyzed.

Cabuz makes no mention of nucleic acid amplification, as apparently conceded by the Patent Office (Official Action, page 5, lines 10-12). Instead, the Patent Office cites Iqbal et al. to show nucleic acid amplification.

However, this secondary reference also fails to disclose or suggest forcing a sample in a first direction through a filter which retains biological particles containing an analyte of interest, and then removing the biological particles from the filter by a flush flow in a second direction opposite the first direction, before analyzing the biological particles contained in said flush flow by means of a nucleic acid amplification assay.

In short, the combination of Cabuz and Iqbal et al. fails to disclose or suggest the claimed assay to one of ordinary skill in

U.S. Patent Appln. S.N. 10/579,137  
REQUEST FOR RECONSIDERATION

**PATENT**

the art. Reconsideration and withdrawal of the obviousness rejection of claims 18-30 over Cabuz in view of Iqbal et al. are respectfully requested.

It is believed the application is in condition for allowance. Reconsideration and withdrawal of the obviousness rejection of claims 18-30, and issuance of a Notice of Allowance directed to those claims, are respectfully requested. The Examiner is urged to telephone the undersigned should she believe any further action is required for allowance of this application.

The extension fee is being paid electronically today. It is not believed any additional fee is required for entry and consideration of this Request for Reconsideration. Nevertheless, the Commissioner is authorized to charge Deposit Account No. 50-1258 in the amount of any such required fee.

Respectfully submitted,

/James C. Lydon/

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